



IFW

Docket No.: 3749-0109PUS1  
(PATENT)

**UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Atsushi MARUYAMA et al.

Application No.: 10/566,383

Confirmation No.: 5509

Filed: January 30, 2006

Art Unit: N/A

For: PARTIALLY DOUBLE STRANDED  
NUCLEIC ACID MOLECULES

Examiner: Not Yet Assigned

**LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on January 30, 2006, attached hereto is an English translation of the International Preliminary Report on Patentability (Form PCT/IB/338) that should be made of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: AUG - 7 2006

Respectfully submitted,

By   
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Attachment(s)

From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

Date of mailing (day/month/year)  
01 June 2006 (01.06.2006)

Applicant's or agent's file reference  
FP-032PCT

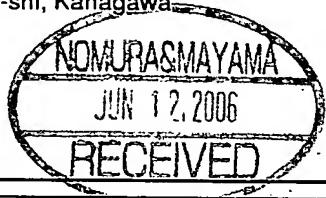
International application No.  
PCT/JP2004/010916

Applicant

THE CIRCLE FOR THE PROMOTION OF SCIENCE AND ENGINEERING et al

To:

NOMURA, Kenichi  
Nohki-kaikan Fourth Floor, 30-1, Tsuruyacho 3-chome,  
Kanagawa-ku, Yokohama-shi, Kanagawa  
2210835  
JAPON

**IMPORTANT NOTIFICATION****1. Transmittal of the translation to the applicant.**

- The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).
- The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

**It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.**

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Faxsimile No.+41 22 740 14 35

Authorized officer

Yoshiko Kuwahara

Faxsimile No.+41 22 338 90 90

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference <b>FP-032PCT</b>	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. <b>PCT/JP2004/010916</b>	International filing date ( <i>day/month/year</i> ) <b>30 July 2004 (30.07.2004)</b>	Priority date ( <i>day/month/year</i> ) <b>30 July 2003 (30.07.2003)</b>	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant <b>THE CIRCLE FOR THE PROMOTION OF SCIENCE AND ENGINEERING</b>			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |                                                                                                                                                                 |
|-------------------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report                                                                                                                                             |
| <input type="checkbox"/>            | Box No. II   | Priority                                                                                                                                                        |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability                                                                |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention                                                                                                                                      |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited                                                                                                                                         |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application                                                                                                                |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application                                                                                                           |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

Date of issuance of this report  
**22 May 2006 (22.05.2006)**

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer  <b>Yoshiko Kuwahara</b>
Facsimile No. +41 22 740 14 35	Telephone No. +41 22 338 90 90

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

**PCT**

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

		Date of mailing (day/month/year)
Applicant's or agent's file reference <b>FP-032PCT</b>		<b>FOR FURTHER ACTION</b> See paragraph 2 below
International application No. <b>PCT/JP2004/010916</b>	International filing date (day/month/year) <b>30.07.2004</b>	Priority date (day/month/year) <b>30.07.2003</b>
International Patent Classification (IPC) or both national classification and IPC		
Applicant <b>THE CIRCLE FOR THE PROMOTION OF SCIENCE AND ENGINEERING</b>		

<p>1. This opinion contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the opinion</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input type="checkbox"/> Box No. VI Certain documents cited</li> <li><input type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>	<p>2. <b>FURTHER ACTION</b></p> <p>If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.</p> <p>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</p> <p>For further options, see Form PCT/ISA/220.</p> <p>3. For further details, see notes to Form PCT/ISA/220.</p>
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Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/010916

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
 This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material  
 in written format  
 in computer readable form
  - c. time of filing/furnishing  
 contained in the international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
**PCT/JP2004/010916**

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																			
<p><b>1. Statement</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Novelty (N)</td> <td style="width: 60%;">Claims    <u>2-4, 9-13, 15, 16</u></td> <td style="width: 20%; text-align: right;">YES</td> </tr> <tr> <td></td> <td>Claims    <u>1, 5-8, 14</u></td> <td style="text-align: right;">NO</td> </tr> <tr> <td>Inventive step (IS)</td> <td>Claims    _____</td> <td style="text-align: right;">YES</td> </tr> <tr> <td></td> <td>Claims    <u>1-16</u></td> <td style="text-align: right;">NO</td> </tr> <tr> <td>Industrial applicability (IA)</td> <td>Claims    <u>1-16</u></td> <td style="text-align: right;">YES</td> </tr> <tr> <td></td> <td>Claims    _____</td> <td style="text-align: right;">NO</td> </tr> </table> <p><b>2. Citations and explanations:</b></p> <p>Document 1: WO 00/20643 A (MOSAIC TECHNOLOGIES) 13 April 2000 &amp; US 6238927 B1      Document 2: Kaori Tajima, et al., Simple basic peptides activate DNA strand exchange. Chemistry Letters (May 2003), Vol. 32, No. 5, p. 470-471      Document 3: Kim WJ, et al., DNA strand exchange stimulated by spontaneous complex formation with cationic comb-type copolymer. J Am Chem Soc. (2002), Vol. 124, No. 43, p. 12676-12677</p> <p>[Claims 1, 5-8, and 14]</p> <p>Based on the description in document 1, the inventions of claims 1, 5-8, and 14 lack novelty.</p> <p>Document 1 describes a partially double-stranded nucleic acid molecule comprising a single-stranded nucleic acid molecule that is complementary to a nucleic acid molecule to be detected and a single-stranded nucleic acid molecule that hybridizes with part of that single-stranded nucleic acid molecule; a nucleic acid molecule in which the region assuming the single-stranded structure in the partially double-stranded nucleic acid molecule is a nucleic acid molecule that is complementary to a region containing a recognition site on the nucleic acid molecule to be detected, and this nucleic acid molecule is immobilized on a solid phase; a thin plate is also included as the solid phase, and detection of the nucleic acid molecule is performed by release of a detection probe.</p> <p>[Claims 2, 3, and 11]</p> <p>Based on the description in document 1, the inventions of claims 2, 3, and 11 lack an inventive step.</p> <p>This examination finds that when detecting a target gene using the nucleic acid molecule described in document 1, persons skilled in the art can suitably establish the length of the single-stranded structure and the double-stranded structure so that hybridization with the target gene will occur efficiently, and select sites having SNPs as the target gene.</p> <p>[Claims 4, 9, 10, 12, 13, 15, and 16]</p> <p>Based on the descriptions in documents 1-3, the inventions of claims 4, 9, 10, 12, 13, 15, and 16 lack an inventive step.</p> <p>Documents 2 and 3 state that a cationic polymer stabilizes a DNA polymer faster than CTAB, and they describe a method for detecting a target gene wherein when detecting a target gene using two target probes, one probe is labeled with the energy donor FITC and the other probe is labeled with the energy acceptor TAMRA, and before detection of the gene FITC and TAMRA are in a darkened state due to quenching, but when the one probe hybridizes and the other probe is released, fluorescence is restored.</p>			Novelty (N)	Claims <u>2-4, 9-13, 15, 16</u>	YES		Claims <u>1, 5-8, 14</u>	NO	Inventive step (IS)	Claims    _____	YES		Claims <u>1-16</u>	NO	Industrial applicability (IA)	Claims <u>1-16</u>	YES		Claims    _____	NO
Novelty (N)	Claims <u>2-4, 9-13, 15, 16</u>	YES																		
	Claims <u>1, 5-8, 14</u>	NO																		
Inventive step (IS)	Claims    _____	YES																		
	Claims <u>1-16</u>	NO																		
Industrial applicability (IA)	Claims <u>1-16</u>	YES																		
	Claims    _____	NO																		

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/010916

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V.

This examination finds that when detecting a target gene using the nucleic acid molecule described in document 1, persons skilled in the art can easily conceive of labeling with a donor fluorescent dye and an acceptor fluorescent dye, establishing the length of the single-stranded-structure and double-stranded structure so that hybridization with the target gene will occur efficiently in that process, and performing hybridization in the presence of a cationic polymer.